



# DoD/FDA Shelf Life Extension Program (SLEP)



**JRCAB -SLEP**



## ***JRCAB History and Mission***

- Began in 1945 as the Army-Navy Specification Cataloging Committee
- In 1984 became the Defense Medical Standardization Board (DMSB)
- 1986 DMSB tasked as Quad Service interface to the FDA for the DoD/FDA SLEP
- In 1998 name provisionally changed to Joint Readiness Clinical Advisory Board (JRCAB)
- In 2002, FDA allowed the National Strategic Pharmaceutical Stockpile (NSPS) to be added to the DoD/FDA SLEP under the JRCAB interface to the FDA
- 2003- updating and moving the automation for DoD/FDA SLEP to an Oracle/Web system

### **MISSION**

- **Maintain the DoD/FDA Shelf Life Extension Program**
- **Provide standardized clinical patient treatment protocols for patient conditions (PCs)**
- **Standardized medical materiel/resources for delivery of healthcare in deployable medical systems (DEPMEDS) and in the Military Health Services System**

# ***DoD/FDA Shelf Life Extension Program***



- **All Pharmaceuticals are controlled by the FDA**
- **New products (including new manufacturers or change in packaging/manufacturing) are given a maximum of a 2 year Shelf Life**
- **The DoD/FDA SLEP is limited to:**
  - Army                      Air Force    DSCP (does not currently**
  - Navy    Marines                      participate)**
  - National Strategic Pharmaceutical Stockpile**
- **NO other Federal or Civilian agency may legally use the program**



## ***DoD/FDA Shelf Life Extension Program***

- **Substantial investments in replacement costs for war reserve potency dated medical material**
  - **Replacement cost in 1986 - \$2.5 million subject of GAO Audit**
- **July 1985 - AF/SG office and FDA met**
  - **Established pilot project for concept testing**
  - **FDA established test protocols for 56 listed items**
  - **Samples of 56 items were sent to the FDA**

# ***DoD/FDA Shelf Life Extension Program***



- **Results from 1122 lots (96 drug products) were evaluated.**
  - **84% of the lots were extended for an average of 57 months past the original expiration date.**
  - **Of the 946 lots extended, 14% were eventually terminated due to failure. The rest are still active or discontinued by the military.**
  - **22 Drug Products showed no signs of stability failure (at least 5 lots of each tested).**
  - **10 Drug Products were unstable with most lots failing initial extension, e.g. Water Purification Tabs**
- **Stability Period is highly variable from lot to lot.**



## ***DoD/FDA Shelf Life Extension Program***

**January 1986 - interagency agreement was signed forming the program**

- **DMSB tasked as Quad-Service focal point**
- **Testing began FY 1987**
  - **4 new projects initiated - total replacement cost avoidance of \$3 million**
- **In FY 1991 FDA increased dedicated**

# *DoD/FDA Shelf Life Extension Program*



**JRCAB serves as Liaison between services /NSPS & FDA**

**Services submit Samples for testing**

**FDA tests Military/contingency significant medications**

**Cost Avoidance to DoD Of \$30M for \$0.6M of testing in FY02**

**FDA grants extension or denies extension of shelf-life, by Lot and NSN**



# ***DoD/FDA Shelf Life Extension Program***

- **Current testing focuses on military significant items**
  - **Drugs that are manufactured specifically for military use - e.g. auto-injectors**
  - **Drugs that are purchased in very large quantities for specific contingency needs - e.g. Ciprofloxacin**
  - **Items that can not be returned through Returns Programs**

- **Other drug products are considered on a case-by-case basis**

- **Factors weighed for decision**







## ***DoD/FDA Shelf Life Extension Program***

### ➤ **Test selection criteria:**

- **Item cannot be a biological**
- **FDA must have a test protocol for the item**
- **Manufacturer's data for the item does not indicate previous instability**
- **Cost beneficial for testing**

➤ **FDA requests samples, various storage locations and lots, through JRCAB to the Service field agency**



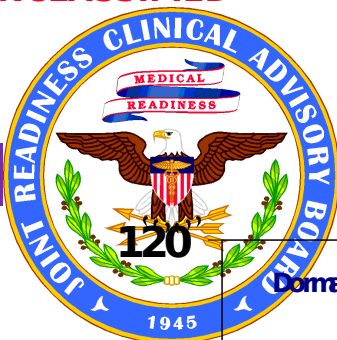
## ***DoD/FDA Shelf Life Extension Program***

- **Field activities send samples to the FDA**
- **Products are tested and results are reported to the JRCAB**
- **JRCAB updates SLEP database, computes financial benefit and cost, orders labels (Dec 03) and distributes the information to the appropriate Service field agency**
- **Tested products are re-tested annually**

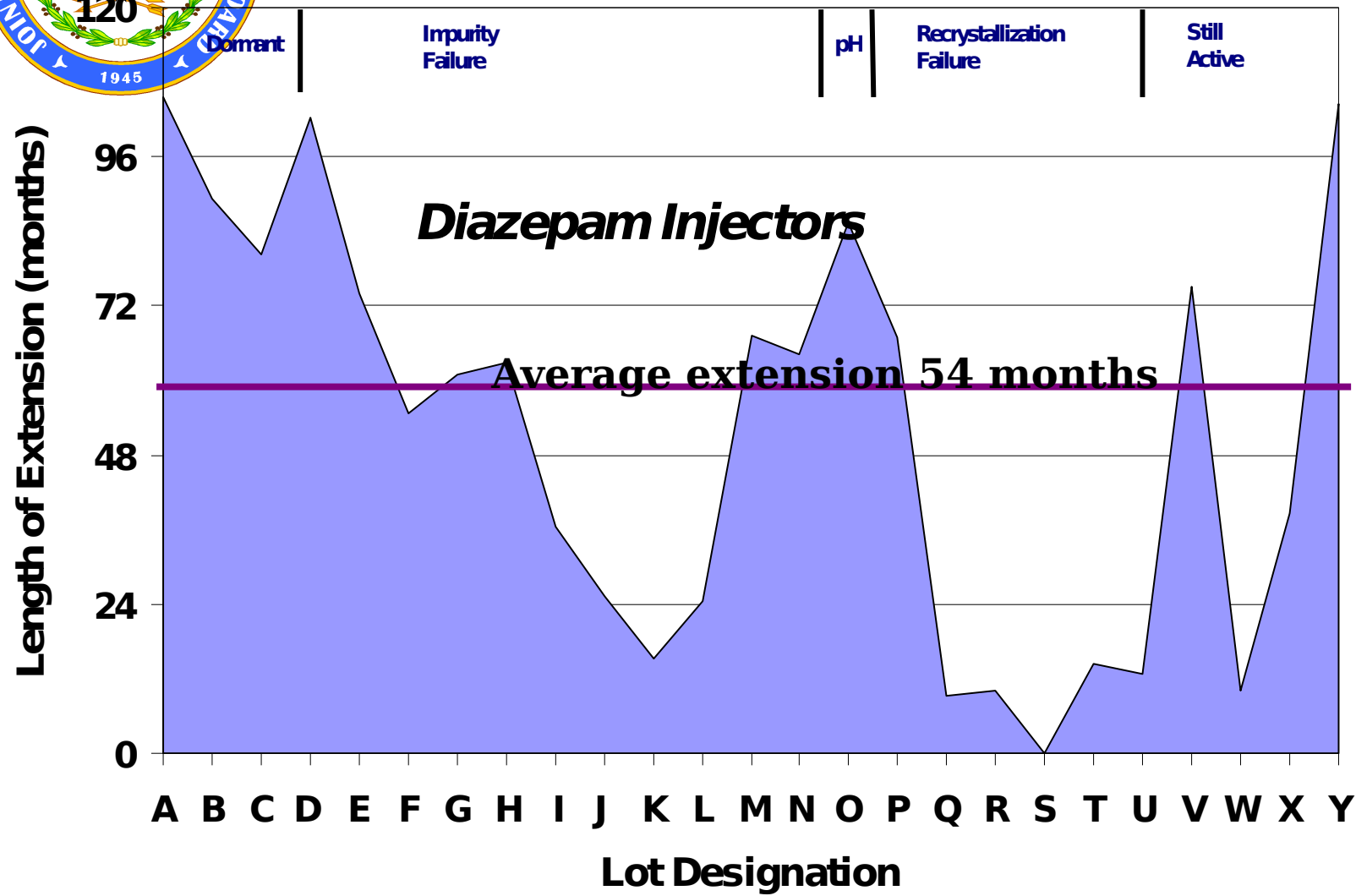


## ***FDA Testing***

- **Test protocols from manufacturer's original product test data**
- **Accelerated testing (stress testing)**
  - Designed to increase rate of chemical or physical degradation using exaggerated storage conditions
- **Potency of stressed samples compared to standard for each item**
  - Results in estimated extendible life of the product



*Extension  
Example*





# ***DoD/FDA Shelf Life Extension Program***

- **FDA testing time-frame**
  - 8 months from the time the JRCAB presents a project candidate list until project's extension information received by JRCAB
- **FDA testing is comprehensive and scientifically sound**
  - Date extensions are conservative estimates of useful life of the product as substantiated by stress testing
- **FDA grants extensions for all DoD facilities having the tested material stored under same conditions**
  - Material specified by manufacturer, expiration date, lot number and storage condition



# ***DoD/FDA Shelf Life Extension Program***

- **Average cost avoidance ratio is \$55 for each dollar spent on testing. This will be reduced, with the new FDA mandate on relabeling. Estimate of new cost avoidance ratio is \$50.00**
- **Sample of cost for testing a lot is:**
  - **Atropine Injectors      \$1850.00**
  - **Ciprofloxacin            \$1800.00**
  - **2-Pam chloride          \$1000.00**
  - **CANA                        \$2500.00**



# ***FDA Re-labeling Requirements***

- **Food and Drug Administration Relabeling Mandate 2002**
- **Labels will be centrally contracted and distributed**
- **SLEP labels will be automatically printed upon extension**





# ***DoD/FDA Shelf Life Extension Program***

## ➤ **New Innovations :**

- **Converting SLEP data base to Oracle/Web based**
- **Centralized, automated ordering and shipping of labels for extensions**
- **Addition of new products to program through the NSPS**
- **Addition of contract support**
- **Increase interface with other DoD and DoD SLEP systems, e.g. JMAR, DoD SLEP ...**